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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/709,020      | 11/08/2000  | Christoph Benning    | MSU-04769           | 3130             |

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EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/709,020

Applicant(s)

BENNING ET AL.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on December 3, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,13 and 15-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,13 and 15-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Claims 1, 13 and 15-40 are pending.

***Claim Rejections - 35 USC § 103***

***Response to Arguments***

Applicant's arguments filed on December 3, 2003, with respect to the rejection(s) of claim(s) 1, 13 and 15-40 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new prior art references.

Claims 1, 13, 15-22 and 35-39 are rejected under 35 U.S.C. 103(a) as being obvious over Benning and Essigmann et al. in view of McNally et al.

Benning (form PTO-1449 - *Annual Review of Plant Physiology & Plant Molecular Biology*, 1998, Vol. 49 Issue 1, p53-75) teach SQDG biosynthesis using a SQDB protein and a sqdX protein (page 61, 2<sup>nd</sup> paragraph). Benning teaches the use of a SQDB protein for the production of UDP-SQ from UDP-glucose and the use of a sqdX protein for the production of SQDG from UDP-SQ (figure 3, page 62). Benning teaches that sqdX from *Synechococcus* sp. catalyzes the reaction of UDP-SQ into SQDG. SqdX is identical to SEQ ID NO:1 of the instant invention, as evidenced by Guler et al. (page 545, 1<sup>st</sup> paragraph – cited on previous form PTO-892).

Benning also teach that sulfite can be used as the sulfur donor (page 66, 2<sup>nd</sup> paragraph). Benning et al. also teach that SQDG of photosynthetic bacteria and plants are a promising anti-tumor and anti-HIV therapeutic (page 54, 1<sup>st</sup> paragraph).

The difference between the reference of Benning and the instant invention is that the reference of Benning does not teach a method of producing UDP-SQ from UDP-glucose with the polypeptide encoded by SEQ ID NO:6.

Essigmann et al. (cited on previous form PTO-892) teach a polypeptide, plant SQD1, that catalyzes the formation of a UDP-sulfoquinovose from UDP-glucose and is orthologous to the SQDB protein of Benning (page 31, 4<sup>th</sup> paragraph and page 39). The SQD1 gene is 100% identical to SEQ ID NO:6 of the instant invention (GenEmbl database – Accession # AF022082). Essigmann et al. teach that said SQD1 gene and the bacterial SQDB gene of Benning are the only sulfolipid genes known to be conserved between different organisms (page 31, 5<sup>th</sup> paragraph).

Although Essigmann et al. states that the sulfur donor is unknown, Essigmann et al. teaches that a sulfite is a plausible sulfur donor (page 40, 3<sup>rd</sup> paragraph).

Regarding co-expression of the two enzymes, co-expression of two different proteins are well known and practiced in the art (Dong et al., Kovach et al. and Yue et al. – form PTO-892). For example, McNally et al. (form PTO-892) teach transformation and co-expression of heterologous proteins in *E. coli* (abstract and pages 7270-7271). McNally uses two vectors conferring different antibiotic resistance to the transformed *E. coli* host cells (page 7271). McNally teach that co-expression in *E. coli* may prove to be a useful approach for studying macromolecular assembly (page 7270) and it is well

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known in the art that expression systems that produce several gene products simultaneously are very useful in synthesis of products involving consecutive enzymatic processes (Bishop et al., previously cited on form PTO-892).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute the SQDB protein of Benning with the SQD1 protein of Essigmann et al. using recombinant techniques readily available in the art. Since the SQD1 gene and the bacterial SQDB gene are the only sulfolipid genes known to be conserved between different organisms, one of ordinary skill in the art would have been motivated to interchange the two proteins, possibly to increase the efficiency of SQDG synthesis. It would have been obvious to one having ordinary skill in the art to carry out the synthesis of SQDG in one system or carrying out the synthesis sequentially. The motivation of making SQDG in once process where both enzymes are present is that steps in purifying the intermediate product maybe avoided. Alternatively, the motivation of making SQDG in multiple steps is that isolation/purification of the intermediate product may increase the efficiency of the catalysis. An efficient production of SQDG is attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics. One of ordinary skill in the art would have had a reasonable expectation of success since Benning outlines the pathway for SQDG production and production of a product using heterologous or orthologous enzymes are routinely performed in the art. Further, co-expression of different proteins using vectors having different selectable markers are well known and practiced in the art.

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Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benning and Essigmann et al. in view of McNally et al. as applied to claims 1, 13, 15-22 and 35-39 above, and further in view of Bidney et al.

The combined references of Benning, Essigmann et al. and McNally et al. teach a method of producing sulfoquinovosyl diacylglycerol, as discussed above.

The difference between the combined teachings of Benning, Essigmann et al. and McNally et al. and the instant invention is that the cited references do not teach expression of the two proteins in monocotyledonous and dicotyledonous cells.

Bidney et al. (U.S. Patent No. 6,265,638 – cited on previous form PTO-892) teach a method of co-expressing heterologous proteins in monocotyledonous and dicotyledonous plant cells using binary or multiple vectors (abstract and Columns 1-20). Bidney et al. teach that the advantage of Agrobacterium-mediated gene transfer system is that it offers the potential to regenerate transgenic cells at relatively high frequencies without a significant reduction in plant regeneration rates (Column 1, lines 17-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to transform plant cells with the method taught by Bidney. The motivation to use Agrobacterium-mediated gene transfer system is to regenerate transgenic cells at relatively high frequencies. One of ordinary skill in the art would have had a reasonable expectation of success since production of heterologous proteins in plant cells are performed routinely in the art.

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Claims 1, 13, 15-16, 26-31 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over Benning, Essigmann et al. and McNally et al. in view of Bevan et al.

Benning, Essigmann et al. and McNally et al. in combination teach a method of making SQDG biosynthesis using a SQDB protein and a sqdX protein, as discussed above.

The difference between the references and the instant invention is that the references do not teach a method of producing SQDG from UDP-SQ with the polypeptide encoded by SEQ ID NO:3.

Bevan et al. (cited on previous form PTO-892) teach a sqdX gene which is 100% identical to SEQ ID NO: 3. The sqdX protein of Bevan et al. and the sqdX protein of Benning et al. are both from *Cyanobacterium synechococcus*.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute the sqdX protein of Benning with the sqdX enzyme of Bevan et al. Since the sqdX proteins of Benning and Bevan are homologous proteins, one of ordinary skill in the art would have been motivated to interchange the two enzyme, possibly to increase the efficiency of SQDG synthesis. It would have been obvious to one having ordinary skill in the art to carry out the synthesis of SQDG in one system or carrying out the synthesis sequentially. The motivation of making SQDG in once process where both enzymes are present is that steps in purifying the intermediate product maybe avoided. Alternatively, the motivation of making SQDG in multiple steps is that isolation/purification of the intermediate product may increase the efficiency of the catalysis. An efficient production of SQDG is

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attractive because sulfolipids are possible anti-tumor and anti-HIV therapeutics. One of ordinary skill in the art would have had a reasonable expectation of success since Benning outlines the pathway for SQDG production and production of a product using heterologous or orthologous enzymes are routinely performed in the art. Further, co-expression of different proteins using vectors having different selectable markers are well known and practiced in the art.

Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benning, Essigmann et al. and McNally et al. and Bevan et al. as applied to claims 1, 13, 15-16, 26-31 and 40 above, and further in view of Bidney et al.

The combined references of Benning, Essigmann et al. and McNally et al. and Bevan et al. teach a method of producing SQDB, as discussed above.

The difference between the references and the instant invention is that the cited references do not teach transformation of monocotyledonous and dicotyledonous plant cells.

Bidney et al. (U.S. Patent No. 6,265,638) teach a method of co-expressing heterologous proteins in monocotyledonous and dicotyledonous plant cells using binary or multiple vectors (abstract and Columns 1-20). Bidney et al. teach that the advantage of Agrobacterium-mediated gene transfer system is that it offers the potential to regenerate transgenic cells at relatively high frequencies without a significant reduction in plant regeneration rates (Column 1, lines 17-21).



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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to transform plant cells with the method taught by Bidney. The motivation to use Agrobacterium-mediated gene transfer system is to regenerate transgenic cells at relatively high frequencies. One of ordinary skill in the art would have had a reasonable expectation of success since production of heterologous proteins in plant cells are performed routinely in the art.

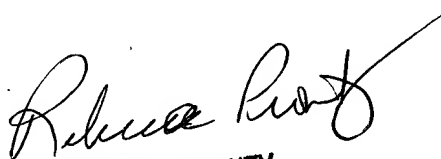
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner

  
REBECCA E. PROUTY  
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